IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

GENUS LIFESCIENCES, INC., Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants, LANNETT CO., INC., Intervenor-Defendant.	Civil Action No. 8:20-cv-03282-PX

GENUS LIFESCIENCES, INC.'S MEMORANDUM OF LAW IN OPPOSITION TO MOTIONS TO DISMISS

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INTRODUCTION

The Food, Drug, and Cosmetic Act ("FDCA") provides that FDA "*shall*, after due notice and opportunity for hearing to the applicant, withdraw approval of an application . . . if [it] finds . . . that the application contains *any* untrue statement of a material fact." 21 U.S.C. § 355(e) (emphasis added). That statute "could not be clearer" in imposing a mandatory duty on FDA to withdraw approval for new drug applications that contain material falsehoods. *Am. Pub. Health Ass'n v. Veneman*, 349 F. Supp. 1311, 1315 (D.D.C. 1972). And FDA cannot evade that duty by closing its eyes, covering its ears, and refusing to make any finding when presented with clear evidence of material untruths in an approved application. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) (FDA must withdraw approval if it "discovers" a triggering condition under § 355(e)). When FDA becomes aware of such clear evidence, it must initiate proceedings to withdraw approval.

Almost a year ago, Genus Lifesciences, Inc. notified FDA that there were material untrue statements in an approved application filed by Genus's competitor, Lannett Company, for a cocaine-based drug called Numbrino. Lannett told FDA that it would manufacture the drug in Cody, Wyoming, and submitted data from the Cody site to FDA in the Chemistry, Manufacturing, and Controls section of its application. But Lannett shut down its Cody facilities, laid off their employees, sold or removed their manufacturing equipment, and—to top it off—leased one of the facilities to Kanye West's shoe company months before FDA approved Lannett's application. These facts are not in genuine dispute: Lannett's CEO confirmed in public statements while its application was pending that Lannett had "ceased operations" in Cody and

transferred manufacturing to a facility in Carmel, New York. Yet Lannett continued to tell FDA that it would manufacture Numbrino in Cody—even doing so in a supplemental filing in November 2019 *after* it had shuttered those facilities.

If Lannett had told FDA the truth, it would have had to amend its application and gather and submit new data (including new exhibit batches of Numbrino) from the Carmel facility. That would have resulted in a lengthy delay in approval. Through its untrue statements, Lannett took an improper shortcut to get to market much faster. And while Lannett protests that it did eventually tell FDA about the switch *after* FDA had approved Numbrino, the fact that FDA has established procedures for drug manufacturers to change their manufacturing facilities *after approval* does not entitle a manufacturer to game the system by concealing from FDA a change made *before approval*. When FDA approved Lannett's application, it had no idea that Lannett had closed the Cody facility, and Lannett had not provided FDA with the data for the Carmel facility that FDA would normally review before approval. As a result, FDA could not properly evaluate whether "the facilities and controls used for . . . the manufacture . . . of [the] drug" were "[a]dequate to preserve its identity, strength, quality, and purity," as the FDCA requires. 21 U.S.C. § 355(d)(3).

Despite being aware of Lannett's untrue statements, FDA has so far refused to take any action to initiate withdrawal proceedings for Numbrino. FDA has not indicated that it has any plans to do so, and it has offered no explanation whatsoever for its prolonged inaction. Genus thus brought this suit under the Administrative

Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, to compel FDA to comply with its mandatory statutory duty to commence withdrawal proceedings.

FDA and Lannett seek dismissal and raise a litany of arguments. They argue that Genus lacks standing, that FDA's inaction is immune from judicial review under the APA, and that Genus should have presented its information to FDA in the form of a citizen petition. Lannett also argues that Genus's complaint fails to plausibly allege that Lannett's application contained material untrue statements or that FDA's delay in acting on those statements is unreasonable; notably, FDA does not join in those arguments. All of FDA's and Lannett's grounds for dismissal are unavailing:

First, Genus has standing to bring this action. FDA's failure to withdraw Numbrino's approval has caused Genus to suffer financial harm, a classic injury-in-fact that is redressable by a judicial order compelling FDA to take the statutorily required action. *See Zeneca, Inc. v. Shalala*, 213 F.3d 161, 170 n.10 (4th Cir. 2000) ("[A] firm has constitutional standing to challenge a competitor's entry into its market."). And as a direct competitor of Lannett, Genus's interest in not having to compete with those who lie to FDA in their new drug applications is within the "zone of interests" protected by the statute. *See TAP Pharm. v. HHS*, 163 F.3d 199, 207 (4th Cir. 1998) ("[C]ommercial competitors of the entities directly regulated by [a] statute satisfy the zone of interests test.").

Second, where (as here) FDA is presented with clear evidence of material untrue statements in an approved application, whether to initiate withdrawal proceedings is not "committed to agency discretion by law." FDA and Lannett do not

dispute that § 355(e) contains mandatory language requiring FDA to withdraw approval for new drug applications that are found to contain untrue statements of material fact. And contrary to FDA's and Lannett's arguments, FDA cannot evade that mandatory duty by ignoring clear evidence and refusing to make the predicate finding to trigger its duty to withdraw approval.

Third, an aggrieved party is not required to file a citizen petition (and submit to potentially never-ending administrative delay) before seeking relief for an agency's unreasonable delay in taking statutorily mandated action. And even if it were, filing a citizen petition would be futile here, where Genus already presented FDA with all the information necessary to trigger FDA's duty to withdraw approval, FDA received that information without objection, and FDA never suggested that presenting that information in the form of a citizen petition would make any difference.

Fourth, Genus's complaint plausibly alleges that FDA's delay in initiating withdrawal proceedings is unreasonable. By the time the Court considers these motions, at least a year will have elapsed since Genus first notified FDA of Lannett's untrue statements—more than the amount of time the statute provides for FDA to review a new drug application in its entirety. Given the statute's unambiguous command and the clarity of the evidence of Lannett's false statements, a delay of that length in initiating withdrawal proceedings is plainly unreasonable.

Fifth, Genus's complaint plausibly alleges that Lannett's application contained material untrue statements. It is beside the point that FDA regulations allowed Lannett to move to a different manufacturing facility *after* approval; those

regulations did *not* allow Lannett to misstate the location and status of its facility *while its application was pending*. And given the central role that the manufacturing facility plays in FDA's review of the Chemistry, Manufacturing, and Controls section of a new drug application, there can be no question that misidentifying that facility is material. If an applicant makes an untrue statement about where a drug will be manufactured, FDA cannot properly perform the "facilities and controls" evaluation mandated by 21 U.S.C. § 355(d)(3), as FDA will be focused on the wrong facility.

FDA's and Lannett's motions to dismiss should be denied.

BACKGROUND

A. Statutory and Regulatory Framework

The FDCA requires a drug company to submit an application and obtain FDA's approval before selling a new drug. *See* 21 U.S.C. § 355(b)(1). The application must contain sufficient information for FDA to evaluate the drug's safety and efficacy. Among other things, the applicant must show that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of [the] drug are [a]dequate to preserve its identity, strength, quality, and purity." *Id.* § 355(d)(3).

To meet that requirement, the applicant must prepare a Chemistry, Manufacturing, and Controls ("CMC") section demonstrating that its quality systems satisfy FDA's current good manufacturing practices ("CGMP") regulations. *See* 21 C.F.R. § 210.1(a). The CMC section must describe the facilities, controls, and processes that will be used to manufacture the drug, including information about the steps in the manufacturing process, the specific pieces of equipment that will be used, and the process controls used at the manufacturing facility. Compl. ¶¶ 12–17. The

CMC section must also include data on three exhibit batches manufactured by the applicant at the proposed manufacturing facility, including six months of accelerated stability data and twelve months of long-term stability data. *Id.* ¶¶ 16, 26.

The information in the CMC section is specific to the facility at which an applicant plans to manufacture the proposed drug. For this reason, the CMC section must identify the name and address of each facility that will be involved in the manufacturing, processing, packaging, labeling, and testing for both the drug substance (i.e., the active ingredient) and the drug product (i.e., the finished product). *Id.* ¶ 17; *see* 21 C.F.R. § 314.50(d)(1)(i)–(ii).

To ensure that each manufacturing facility conforms to CGMP requirements, FDA reviews the CMC section, conducts a Pre-Approval Facility Evaluation, and determines whether to physically inspect the facility before approving the application. Compl. ¶¶ 18–21. When making that determination, FDA considers factors such as the facility's inspection and performance history, the risks associated with the new drug product and the manufacturing process, and the existence of inaccurate or unreliable information in the new drug application. *Id.* ¶ 19. If a physical inspection is deemed necessary, FDA may conduct a Pre-Approval Inspection of a facility. *Id.* ¶ 20. If the evaluation process shows that the manufacturing facility is inadequate to ensure the identity, strength, quality, and purity of the drug, then FDA must deny the application. *Id.* ¶ 22; *see* 21 U.S.C. § 355(d); 21 C.F.R. § 314.125.

If an applicant wishes to change a manufacturing facility named in a pending application, FDA regulations require the applicant to amend the application with

revised information for the new facility. Compl. ¶¶ 23–27. Among other things, the amendment would need to include (1) data from three exhibit batches of the drug produced at the new manufacturing site, including twelve months of long-term stability data and six months of accelerated stability data; and (2) revised labeling with information for the new manufacturing facility. *Id.* ¶¶ 26–27.

If FDA "discovers after approval that" an application contained an untrue statement of material fact, FDA must withdraw approval. *Brown & Williamson*, 529 U.S. at 134 (discussing 21 U.S.C. § 355(e)). Congress mandated in no uncertain terms that FDA "*shall*, after due notice and opportunity for hearing to the applicant, withdraw approval of an application . . . if [it] finds . . . that the application contains *any* untrue statement of a material fact." 21 U.S.C. § 355(e) (emphases added).

B. The Material Untrue Statements in Lannett's Application

In September 2017, Lannett submitted a new drug application for Numbrino, a nasal anesthetic containing cocaine hydrochloride as an active ingredient. The CMC section of the application stated that the drug substance and drug product would be manufactured exclusively at a facility located at 601 Yellowstone Avenue in Cody, Wyoming (the "Cody Yellowstone Facility"). Compl. ¶¶ 33, 36. The CMC section also stated that the drug substance raw materials would be held and tested at a facility located at 119 Road 2AB in Cody, Wyoming (the "Cody 119 Facility"). *Id.* FDA accepted Lannett's application for review in November 2017. *Id.* ¶ 37. The following month, FDA performed a Pre-Approval Inspection of the Cody Yellowstone Facility as part of its review of the Numbrino application. *Id.*

While the application was pending, Lannett publicly announced the closure of the Cody facilities. In a June 2019 SEC filing, Lannett disclosed that it had decided to "sell the equipment and real estate utilized by" the Cody business "and to have Cody Labs cease all operations," with the closure to be "substantially completed by September 30, 2019." *Id.* ¶ 40. In an August 2019 earnings call, Lannett's CEO stated that Lannett had "completed" the process of "ceasing . . . operations at CODY" and "selling the associated equipment." *Id.* ¶ 42. And in a November 2019 earnings call, the CEO confirmed that Lannett had "ceased operations at the Cody plant" and relocated its manufacturing operations to a plant in Carmel, New York (the "Carmel Facility"). *Id.* ¶ 46. He stated that as of November 2019, Lannett had "already produced [Numbrino] at [its] Carmel facility." *Id.* ¶ 55.

Local news also reported on the Cody closures. In June 2019, multiple articles reported on Lannett's announcement that it was ceasing operations in Cody and laying off approximately 80 Cody Labs employees. *Id.* ¶ 41. In September 2019, a newspaper reported that "Cody Laboratories . . . is shut down for good" and said a Lannett spokesperson had confirmed that "Cody Labs equipment has been sold and the company is in the process of selling its real estate." *Id.* ¶ 44. A property listing for the lease of the Cody Yellowstone Facility states that Lannett ceased manufacturing operations there in October 2019. *Id.* ¶ 45. And a December 2019 report stated that Lannett had leased the Cody 119 Facility to Kanye West's shoe company. *Id.* ¶ 47.[1]

[1] The Cody closure was years in the making. According to news reports, Lannett initially sought "to pursue a $50.5 million expansion in Cody," and in 2017 the

Yet Lannett did not tell FDA any of this. Instead, despite the well-documented closure of the Cody facilities in or around September 2019, Lannett continued to misrepresent the Cody Yellowstone Facility as the planned manufacturing site for Numbrino. *See id.* ¶¶ 48–57. And Lannett's failure to come clean with FDA was not for lack of opportunity. On October 31, 2019, FDA sent Lannett an information request directing Lannett to update the Numbrino application "to ensure complete facility information is provided for all facilities used for commercial production." *Id.* ¶ 48. Lannett responded on November 1, 2019 by submitting an updated CMC section for its application. *Id.* ¶ 50. In that submission, Lannett told FDA that it would use the Cody Yellowstone Facility as the exclusive site for "[d]rug substance manufacturing" and "[d]rug product manufacturing" for Numbrino. *Id.* ¶ 51. Lannett also said it would use the Cody 119 Facility for "receipt and sampling of drug substance raw materials." *Id.* Lannett falsely represented that both shuttered facilities were "active" and "ready for inspection." *Id.* Lannett identified the Carmel Facility as one of several sites that would perform "release and stability testing" for Numbrino, but as just explained, it told FDA that it would *manufacture* Numbrino at the Cody Yellowstone Facility, not the Carmel Facility. *Id.* ¶ 52.

Rather than advise FDA of the Cody closure while its application was pending, Lannett waited for FDA to approve the application, which FDA did on January 10,

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Wyoming State Loan and Investment Board approved a $23 million loan for that project. Compl. Ex. H. But in "early 2018," Lannett "halted the expansion project" and turned down the loan. *Id.* Instead, Lannett laid off fifty workers during the summer of 2018 "and then announced in October [2018] that it was putting Cody Labs up for sale." Compl. Ex. F.

2020. *Id.* ¶ 56. Naturally, the FDA-approved label for Numbrino reflected FDA's belief that Numbrino would be manufactured in Cody, Wyoming. *Id.* ¶ 57. Through its untrue statements, Lannett avoided a long delay in getting its application approved. If, in response to FDA's October 31, 2019 request for updated facility information, Lannett had been truthful and told FDA that the Cody facility was no longer operational, that its employees had been laid off and its equipment sold, and that Lannett would instead be manufacturing Numbrino in Carmel, FDA might have conducted a Pre-Approval Inspection of the Carmel Facility. *Id.* ¶ 54. And FDA most certainly would have required Lannett to submit a complete CMC section for the Carmel Facility before approval, including twelve months of long-term stability data and six months of accelerated data for three exhibit batches of Numbrino produced at the Carmel Facility, to permit FDA to evaluate the "facilities and controls" in place as required by the FDCA. *Id.* Being truthful likely would have delayed approval of Lannett's application by at least twenty-one months. *Id.*

Rather than take the time to comply with these critical requirements, Lannett waited for FDA to approve its application. Then, having obtained approval based on false premises, Lannett immediately filed a "Changes Being Effected–30" form requesting FDA's approval to change Numbrino's manufacturing site from Cody to Carmel—months *after* Lannett had publicly announced and completed the closure of the Cody Facility. *See* FDA Mot., Ex. 1, Dkt. 19-2, ¶ 11 ("Abt Decl."). This had been the plan all along: Lannett's CEO stated in November 2019 that Lannett would complete what he euphemistically called the "technical transfer" of the

manufacturing site after FDA approved the application. Compl. ¶ 55. Lannett's plan worked: FDA approved Lannett's change request on March 10, 2020. Abt Decl. ¶ 12.

C. Genus Notifies FDA of Lannett's Untrue Statements

Genus notified FDA of Lannett's false statements in early 2020, but FDA did not take any steps to withdraw approval for Numbrino. Genus first wrote FDA on February 11, 2020 to object to Lannett's CBE–30 request. In that letter, Genus put the agency on notice that Lannett had closed the Cody, Wyoming manufacturing facilities and transferred production to the Carmel Facility months before FDA approved the Numbrino application. Compl. ¶ 60. Genus wrote to FDA a second time on March 18, 2020 to point out (what should have been obvious) that Lannett's false statements also required the agency to withdraw approval of Lannett's Numbrino application under 21 U.S.C. § 355(e). *Id.* ¶ 61. Genus's letters explained the Numbrino application timeline described above and cited numerous publicly available sources—including SEC filings, earnings call transcripts, and news reports—demonstrating Lannett's untrue statements. *Id.* ¶¶ 60–61.

FDA did not respond to Genus's letters. Genus followed up on June 30, 2020 to notify FDA that it was preparing to file this suit to compel FDA to withdraw approval for Numbrino. *Id.* ¶ 62. FDA agreed to meet to discuss the issue via teleconference on August 13, 2020. *Id.* At that meeting, Genus walked a group of senior FDA officials through a detailed timeline of Lannett's false statements, complete with publicly available evidence. FDA did not take issue with Genus's evidence or arguments and did not dispute that Lannett's application contained untrue statements of material fact. *Id.* ¶ 63. Yet FDA did not agree to withdraw approval, and to this day—almost

a full year after Genus first brought the matter to the agency's attention—FDA has never taken any public steps toward withdrawing Lannett's approval for Numbrino, nor has it provided any explanation for its failure to do so. *Id.*

ARGUMENT

I. Genus has standing to challenge FDA's failure to withdraw approval of Numbrino.

FDA argues that Genus has failed to satisfy the injury-in-fact and redressability requirements for Article III standing, along with the "zone of interests" test for statutory standing. Lannett admits that Genus has an injury-in-fact but joins FDA's other standing arguments. FDA and Lannett are wrong on all counts.

A. Genus has Article III standing.

Genus has Article III standing because FDA's prolonged inaction is allowing a competitor's drug to remain on the market, thereby reducing Genus's market share. The resulting economic harm to Genus easily meets the threshold for a constitutional injury, and that harm would be redressable by an order compelling FDA to adhere to its statutory mandate.

To establish Article III standing, a plaintiff must allege (1) that it suffered an "injury in fact" that "is concrete and particularized, as well as actual or imminent"; (2) that it is "likely that the injury was caused by the conduct complained of and not by the independent action of some third party not before the court"; and (3) that it is "likely, and not merely speculative, that a favorable decision will remedy the injury." *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 154 (4th Cir. 2000) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). At the

motion to dismiss stage, a plaintiff need only "plausibly allege" that it meets these requirements. *Liberty Univ., Inc. v. Lew*, 733 F.3d 72, 89 (4th Cir. 2013).

Injury-in-Fact. Genus manufactures Goprelto, a cocaine-based anesthetic that FDA approved in December 2017. Compl. ¶ 5. Lannett's drug Numbrino is Goprelto's direct competitor. Goprelto and Numbrino are the only two FDA-approved drugs that use cocaine hydrochloride as an active ingredient, and both drugs are indicated for the same use: the induction of local anesthesia when performing surgeries or diagnostic procedures on or through patients' nasal cavities. *Id.* ¶ 65. Numbrino's presence in the marketplace thus causes Genus to suffer a loss of market share and corresponding financial harm. *Id.*

Such financial harm easily satisfies the injury-in-fact requirement. "Financial harm," including "lost business opportunities," is "a classic and paradigmatic form of injury in fact." *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 210–11 (4th Cir. 2020) (quotation marks omitted). Accordingly, "[n]umerous cases have found that a firm has constitutional standing to challenge a competitor's entry into its market." *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 170 n.10 (4th Cir. 2000). The Fourth Circuit and other courts have repeatedly held that a drug manufacturer has standing to challenge an agency decision that allows the marketing of a competing drug and thereby reduces the plaintiff's profits. *See id.*; *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998); *MD Pharm., Inc. v. Drug Enforcement Admin.*, 133 F.3d 8, 11 (D.C. Cir. 1998); *Schering Corp. v. FDA*, 51 F.3d 390, 395 (3d Cir. 1995).

Indeed, as FDA points out, Genus has filed a separate lawsuit challenging on other grounds FDA's original decision to approve Lannett's new drug application for Numbrino. *See* FDA Mot. 6 (citing *Genus Lifesciences, Inc. v. Azar*, No. 1:20-cv-00211-TNM (D.D.C.)). Genus's standing to bring that action is based on the same injury at issue here: the economic harm Genus suffers from its competitor's continued presence in the market. Neither FDA nor Lannett contested Genus's standing to bring that action. And here, too, Lannett admits that the economic harm Genus suffers from having to compete with Numbrino "can in principle establish an injury-in-fact." Lannett Mot. 16. Yet FDA insists that Genus lacks Article III standing in this case.

To justify that position, FDA appears to argue that a company has standing to challenge agency action that allows a competitor to *enter* the market, but not agency *in*action that allows a competitor to *remain* in the market. *See* FDA Mot. 21. That is nonsense. The APA allows a party to challenge agency inaction as well as agency action. *See* 5 U.S.C. § 706(1); *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004). When FDA unlawfully approves a new drug application and thereby allows a new drug to enter the market, everyone agrees that a financially injured competitor has an injury-in-fact. When FDA unlawfully fails to withdraw that approval and thereby allows the competitor to remain in the market, the agency's inaction causes the company to suffer *exactly the same* injury-in-fact.

FDA does not cite any case holding that financial harm from increased competition counts as an Article III injury when it results from agency action but not when it results from agency inaction. Nor does FDA identify any logical basis for

drawing such a distinction. Plainly, Genus's undisputed economic injury qualifies as an injury-in-fact. What is more, FDA and Lannett do not dispute (nor could they) that Genus's injury is fairly traceable to FDA's failure to withdraw Numbrino's approval, satisfying the causation requirement for Article III standing.

Redressability. FDA and Lannett argue that Genus's economic injury is not redressable in this case. On their view, even if the Court were to order FDA to initiate withdrawal proceedings, the agency might still decide not to withdraw Lannett's approval for Numbrino—either because FDA might conclude "that there was not any untrue statement of material fact in Lannett's application," Lannett Mot. 16; *see also* FDA Mot. 23, or because FDA might exercise "discretion" not to withdraw approval despite material falsehoods in the application, FDA Mot. 24.

These arguments confuse the merits of this suit with Genus's standing to bring it. Genus claims that Lannett's application clearly contained untrue material statements and that FDA therefore has a *nondiscretionary duty* to withdraw Lannett's approval. If Genus is wrong, the Court may rule for FDA on the merits. But if Genus is right, an order directing FDA to initiate withdrawal proceedings would surely provide relief for Genus's injury. That is all that is required for Genus to have standing. *See Overbey v. Mayor of Baltimore*, 930 F.3d 215, 229 n.14 (4th Cir. 2019) ("[S]tanding in no way depends on the merits of the plaintiff's contention that particular conduct is illegal." (quoting *Warth v. Seldin*, 422 U.S. 490, 500 (1975)).[2]

[2] Any suggestion that Lannett's application did not contain material untrue statements—or that FDA has unreviewable discretion not to withdraw Lannett's approval regardless—is incorrect as explained below. *See* Parts II and V, *infra*.

Regardless, even if it were *possible* for FDA to refrain from withdrawing approval following a hearing, the mere possibility of such an outcome does not defeat redressability. Article III standing requires only that Genus's injury "is *likely* to be redressed by a favorable judicial decision," not that such relief is guaranteed. *Hutton v. Nat'l Bd. of Examiners in Optometry, Inc.*, 892 F.3d 613, 619 (4th Cir. 2018) (emphasis added, quotation marks omitted). Plaintiffs therefore may sue to enforce a procedural administrative requirement "disregard of which *could* impair a separate concrete interest of theirs," even if prevailing in court would not guarantee the agency action that plaintiffs ultimately seek. *Lujan*, 504 U.S. at 572 & n.7 (emphasis added).

In sum, Genus has suffered an injury-in-fact—financial harm from competition with Numbrino—that is fairly traceable to FDA's failure to withdraw Numbrino's approval and that would likely be redressed by an order requiring FDA to initiate proceedings to withdraw approval. Genus therefore has Article III standing.

B. Genus is within the zone of interests.

Next, FDA and Lannett argue that even if Genus has Article III standing, it lacks "prudential standing" because it is outside the "zone of interests" protected by the statute in question. That argument, too, is unavailing.

First of all, FDA's and Lannett's framing of this argument is incorrect and misleading. As the Supreme Court has explained, "'prudential standing' is a misnomer as applied to the zone-of-interests analysis," which simply asks whether the plaintiff "has a right to sue under [a particular] statute." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 (2014) (quotation marks omitted). This inquiry "does not implicate subject-matter jurisdiction." *Id.* at 128 n.4 (quotation

marks omitted); *see Kansas ex rel. Kan. Dep't for Children & Families v. SourceAmerica*, 826 F. App'x 272, 283 (4th Cir. 2020).

In any event, the zone-of-interests test poses no obstacle to this suit. The test requires only that the plaintiff's interest be "arguably within the zone of interests to be protected or regulated by the statute that he says was violated." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (quotation marks omitted). This test "is not meant to be especially demanding." *Id.* at 225 (quotation marks omitted). And where, as here, a plaintiff's cause of action arises under the APA, courts must "apply the test in keeping with Congress's evident intent when enacting the APA to make agency action presumptively reviewable." *Id.* (quotation marks omitted). Moreover, the Supreme Court "ha[s] always conspicuously included the word 'arguably' in the test to indicate that the benefit of any doubt goes to the plaintiff," *id.*—though FDA conspicuously omits that word when it describes the zone-of-interests test. In short, the zone-of-interests test "forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress meant to permit the suit." *Id.* (quotation marks omitted).

Here, Genus's interest in avoiding illegitimate competition from those who lie to FDA in their new drug applications is closely related to the purposes underlying the FDCA in general and § 355(e) in particular. The FDCA's goal is to "ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *Brown & Williamson*, 529 U.S. at 133. The specific provision at issue here, § 355(e), furthers

that goal by seeking to ensure that new drug applications do not contain material untruths. A company injured by having to compete with a drug that was approved based on such untruths—and that therefore cannot have undergone the rigorous premarket review the statute requires—is at least arguably within the zone of interests to be protected by the statute. Surely such a company's interests are not "so marginally related to or inconsistent with" Congress's purpose of ensuring the accuracy of new drug applications that a court should assume Congress meant to bar it from enforcing the statute. *Patchak*, 567 U.S. at 225 (quotation marks omitted).

FDA and Lannett counter that Congress adopted § 355(e) to protect consumers, not competitors. But the zone-of-interests test does "not require any indication of congressional purpose to benefit the would-be plaintiff." *Id.* (quotation marks omitted). Rather, "the salient consideration under the APA is whether the challenger's interests are such that they 'in practice can be expected to police the interests that the statute protects.'" *Amgen, Inc. v. Smith*, 357 F.3d 103, 109 (D.C. Cir. 2004). Because "[c]ongruence of interests, rather than identity of interests, is the benchmark," "[p]arties motivated by purely commercial interests routinely satisfy the zone of interests test." *Id.* Genus's interest in ensuring that its competitors provide accurate information to FDA is certainly congruent with protecting consumers' interest in ensuring that FDA effectively polices drugs' safety and efficacy.

Indeed, competitors of regulated parties are often within the zone of interests protected by a statute. In a pathmarking case, the Supreme Court held that commercial banks were arguably within the zone of interests protected by a statute

limiting membership in credit unions, the banks' competitors, even though the statute was aimed at promoting the credit unions' "safety and soundness" and not at benefiting the banks. *Nat'l Credit Union Admin. v. First Nat'l Bank & Tr. Co.*, 522 U.S. 479, 492–93 & n.6 (1998) ("*NCUA*"). The Fourth Circuit reads *NCUA* as standing for the proposition that "commercial competitors of the entities directly regulated by [a] statute satisfy the zone of interests test." *TAP Pharm. v. HHS*, 163 F.3d 199, 207 (4th Cir. 1998); *see id.* at 208 ("[W]here a statute defines a group that is subject to its provisions, a party asserting commercial interests satisfies the zone of interests test . . . if its interests put it in the same position as a member of the subject group or a commercial competitor of such a member."); *Leaf Tobacco Exps. Ass'n, Inc. v. Block*, 749 F.2d 1106, 1115 (4th Cir. 1984) (the zone-of-interests test "was created . . . to promote competitor standing").

Consistent with the Fourth Circuit's approach, courts have held that drug companies are at least arguably within the zone of interests of statutes that regulate the marketing of competing drugs. For example, the Third Circuit allowed a drug manufacturer to challenge FDA's adoption of an abbreviated process for evaluating the safety and effectiveness of competing generic drugs, reasoning that the manufacturer's interest in "enforc[ing] the entry restrictions imposed upon generic drug manufacturers" was "aligned with" the statutory purpose of ensuring drugs' safety and effectiveness. *Schering Corp.*, 51 F.3d at 395–96. Similarly, the D.C. Circuit permitted a drug company to challenge DEA's approval of a competitor's application under the Controlled Substances Act to produce a generic version of the

drug, holding that the manufacturer was "a suitable challenger" whose interests were congruent with the statute's purpose of protecting the public health. *MD Pharm.*, 133 F.3d at 12–13; *see also Berlex Labs., Inc. v. FDA*, 942 F. Supp. 19, 24 (D.D.C. 1996) (allowing drug company to challenge FDA's decision to approve competing drug without requiring clinical trials; holding that company's interests were "aligned sufficiently" with statutory goal of ensuring "the safety and efficacy of new drugs").

FDA cites (at 28) a handful of cases where the D.C. Circuit held that the zone-of-interests test barred a party from filing suit merely to "increas[e] the regulatory burden on its competitors." *Cement Kiln Recycling Coal. v. EPA*, 255 F.3d 855, 871 (D.C. Cir. 2001); *see Ass'n of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667, 674 (D.C. Cir. 2013); *Hazardous Waste Treatment Council v. EPA*, 861 F.2d 277, 285 (D.C. Cir. 1988). Those cases are inconsistent with controlling precedent in this Circuit, which holds that the zone of interests embraces "the parties expressly subject to the statute *and the commercial competitors of such parties*." *TAP Pharm.*, 163 F.3d at 207 (emphasis added). As then-Judge Kavanaugh pointed out, the cases on which FDA relies are also inconsistent with Supreme Court precedent and with numerous other D.C. Circuit decisions that treat competitors as falling within the zone of interests. *See White Stallion Energy Ctr., LLC v. EPA*, 748 F.3d 1222, 1270–71 (D.C. Cir. 2014) (Kavanaugh, J., concurring in part and dissenting in part), *overruled in part on other grounds*, 576 U.S. 743 (2015). What's more, the cases FDA cites are not on point: Genus is not seeking to increase the regulatory burdens on Lannett, but rather to enforce the conditions Congress placed on Lannett's ability to enter the market *at all*.

Courts have consistently held that a competitor falls within the zone of interests of a statute that imposes "restrictions on potential market entrants." *MD Pharm.*, 133 F.3d at 12–13 (D.C. Cir. 1998); *see Schering Corp.*, 51 F.3d at 395.[3]

In short, Supreme Court precedent, binding Fourth Circuit case law, and a robust consensus of persuasive authority all make clear that Genus's economic interest in not having to compete with a drug whose sponsor made material untrue statements in its application is within the zone of interests protected by § 355(e).

II. FDA does not have unreviewable discretion to ignore material untrue statements in a new drug application.

FDA and Lannett argue that FDA's failure to initiate proceedings to withdraw Numbrino's approval is "committed to agency discretion by law" and therefore outside the scope of judicial review under 5 U.S.C. § 701(a)(2). They are mistaken. Section 355(e) mandates that FDA "shall withdraw approval" when an application is found to have contained any untrue statement of material fact, and FDA cannot evade that statutory command by refusing to make a finding when presented with clear evidence. As the Supreme Court has noted, FDA's duty to withdraw approval is

[3] The cases Lannett cites (at 19) are even farther afield and involve situations where the plaintiff's interests *conflicted* with the interests the statute was meant to protect. *See Taubman Realty Grp. Ltd. P'ship v. Mineta*, 320 F.3d 475, 481 (4th Cir. 2003) (no standing for mall owner that sought to halt construction of a shopping center by invoking statute aimed at promoting commerce by improving interstate highway system); *Leaf Tobacco Exps.*, 749 F.2d at 1115 (no standing for exporters whose suit "would necessarily come at the expense of" farmers who were the statute's "intended beneficiaries"); *Clinton Cmty. Hosp. Corp. v. S. Md. Med. Ctr.*, 510 F.2d 1037, 1038 (4th Cir. 1975) (no standing for hospital whose suit to enjoin construction of competing hospital based on alleged environmental harm to the new hospital "turn[ed] the statutory scheme 180 degrees around").

mandatory whenever FDA "discovers after approval that" one of the conditions in § 355(e) is present. *Brown & Williamson*, 529 U.S. at 134.

A. Section 355(e) creates a mandatory duty to withdraw approval of an application that contains a material untrue statement.

Because "Congress rarely intends to prevent courts from enforcing its directives to federal agencies," FDA "bears a heavy burden in attempting to show that Congress has prohibited all judicial review of the agency's compliance with a legislative mandate." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015). True, "an agency's refusal to initiate enforcement proceedings is not ordinarily subject to judicial review." *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007); *see Heckler v. Chaney*, 470 U.S. 821, 831 (1985). But it is far from clear that withdrawal of approval is the type of "enforcement proceeding" to which *Chaney*'s presumption of non-reviewability applies. Judge Katzmann has argued that withdrawal proceedings under the FDCA are not enforcement actions because they are general, forward-looking, and "essentially legislative in nature"; and, therefore that the decision not to institute such proceedings is presumptively reviewable under the APA. *Nat. Res. Def. Council, Inc. v. FDA*, 760 F.3d 151, 189–90 (2d Cir. 2014) ("*NRDC*") (dissenting opinion).[4]

But even if withdrawal of approval counts as "enforcement," the Supreme Court has been careful to "emphasize that the decision [not to enforce a statute] is only *presumptively* unreviewable; the presumption may be rebutted where the

[4] The majority opinion in *NRDC* found it unnecessary to address "[w]hether a withdrawal action is an enforcement action." 760 F.3d at 175 n.28.

substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Chaney*, 470 U.S. at 832–33 (emphasis added). The APA does not "set agencies free to disregard legislative direction in the statutory scheme that the agency administers." *Id.* at 833. So if Congress "has indicated an intent to circumscribe agency enforcement discretion, and has provided meaningful standards for defining the limits of that discretion, there is 'law to apply' under § 701(a)(2), and courts may require that the agency follow that law." *Id.* at 834–35; *see also Am. Academy of Pediatrics v. FDA,* 379 F. Supp. 3d 461, 480–81 (D. Md. 2019) (explaining the limits on *Chaney*'s presumption).

In § 355(e), Congress made clear its intent to circumscribe FDA's enforcement discretion and supplied a meaningful standard for judicial review. Section 355(e) provides that "[t]he Secretary *shall*, after due notice and opportunity for hearing to the applicant, withdraw approval of an application . . . if the Secretary finds . . . that the application contains *any* untrue statement of a material fact" (emphases added). Congress's use of "shall" indicates that withdrawal of approval is mandatory for applications that are shown to contain material falsehoods. *See Lopez v. Davis*, 531 U.S. 230, 241 (2001) (Congress "use[s] 'shall' to impose discretionless obligations"); *see also, e.g.*, *Navy Fed. Credit Union v. LTD Fin. Servs., LP*, 972 F.3d 344, 356 (4th Cir. 2020). And Congress's use of "any" further confirms that it did not intend FDA

to exercise discretion about *which* material untruths justify withdrawing approval. *See Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219–20 (2008).[5]

Accordingly, at least one court has held that § 355(e) imposes a mandatory duty on FDA that is subject to judicial review. *See Am. Pub. Health Ass'n v. Veneman*, 349 F. Supp. 1311 (D.D.C. 1972). The *Veneman* court held that "it could not be clearer that [FDA] *must* begin the procedures to withdraw a drug when [it] concludes" that a condition in § 355(e)'s first sentence is met. *Id.* at 1315. And it squarely rejected FDA's argument that "[i]t has discretion in the selection of cases to notice for hearing." *Id.* at 1316. The court thus concluded that "the issues presented do not deal with agency discretion and are subject to review under the [APA]." *Id.* at 1315.

Courts have recognized that statutes with similar mandatory language circumscribe agency enforcement discretion and permit judicial review under the APA. *See, e.g.*, *Dunlop v. Bachowski*, 421 U.S. 560, 563 n.2, 567 & n.7 (1975) (where statute provided that Secretary of Labor "shall . . . bring a civil action" to set aside an invalid union election, there was "no merit in the Secretary's contention that his decision is an unreviewable exercise of prosecutorial discretion"), *overruled in part on other grounds*, *Local No. 82, Furniture & Piano Moving v. Crowley*, 467 U.S. 526, 549

[5] FDA claims that in *Chaney*, the Supreme Court "considered the same [statutory] section at issue here" and concluded it did not limit the agency's enforcement discretion. FDA Mot. 11. That is misleading. In *Chaney*, the Court merely noted that the FDCA's "substantive prohibitions of 'misbranding' and the introduction of 'new drugs' absent agency approval" did not limit the agency's "discretion to refuse to initiate enforcement proceedings." 470 U.S. at 835–36 (citing 21 U.S.C. §§ 352(f)(1), 355). The Court had no occasion to consider § 355(e) or any other provision defining circumstances in which FDA "shall" take action.

n.22 (1984); *Armstrong v. Bush*, 924 F.2d 282, 295–96 (D.C. Cir. 1991) ("In contrast to a statute that merely *authorizes* an agency to take enforcement action as it deems necessary, the [Federal Records Act] *requires* the agency head and Archivist to take enforcement action."); *Am. Academy of Pediatrics*, 379 F. Supp. 3d at 485.

FDA and Lannett cite inapposite cases involving statutes that, unlike § 355(e), did *not* mandate discrete agency action. The statute in *Sierra Club v. Larson*, 882 F.2d 128, 129 (4th Cir. 1989), allowed the Secretary of Transportation to withhold federal highway funds from a State that failed to control advertising near highways, while also allowing the Secretary to "suspend the withholding of funds" whenever she determined that doing so was "in the public interest." The statute thus "d[id] not mandate that enforcement actions be taken by anyone." *Id.* Similarly, the statute in *Montgomery County v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006), authorized the HHS Secretary to permit importation of prescription drugs "under such conditions as [he] deem[ed] to be appropriate," and only if he first certified that doing so would not endanger public "health or safety" and would yield a "significant reduction" in costs. *Id.* at 510. The statute's language was "precatory," not mandatory, and did not provide a meaningful standard by which a court could "measure 'safety' or 'significant reduction in cost.'" *Id.* at 513. The statute in *Sierra Club v. Jackson*, 648 F.3d 848 (D.C. Cir. 2011), was also open-ended: It directed the EPA Administrator to "take such measures . . . as necessary to prevent the construction or modification of a major emitting facility," while providing "no guidance . . . as to what action is 'necessary,'" thus leaving that choice "to the Administrator's discretion." *Id.* at 851, 856.

By contrast, § 355(e) mandates a specific, discrete action: withdrawal of approval. And it provides a clear standard for determining when approval must be withdrawn: when an approved application is found to have contained *any* untrue statement of material fact. The statute thus "indicate[s] an intent to circumscribe agency enforcement discretion" and "provide[s] meaningful standards for defining the limits of that discretion." *Chaney*, 470 U.S. at 834–35.

B. FDA cannot evade its duty by refusing to make the predicate finding when presented with clear evidence.

FDA and Lannett appear not to dispute that § 355(e) limits FDA's discretion and requires withdrawal of approval if FDA finds that an application contains a material untruth. Instead, they argue that FDA has unreviewable discretion not to make the predicate finding. In other words, they claim that while Congress gave FDA *no discretion* about what to do upon making such a finding, Congress negated its own command by simultaneously giving the agency *limitless discretion* about whether to make such a finding in the first place. That is untenable. FDA may not evade § 355(e)'s mandate by refusing to make the predicate finding when presented with clear evidence of material untruths. Such a reading would nullify the mandatory nature of "shall" and transform Congress's mandate to withdraw approval of materially false applications into an option that FDA may exercise as it pleases.[6]

[6] Section 355(e) also requires FDA to provide Lannett with "notice and an opportunity for hearing" before withdrawing approval. FDA, but not Lannett, suggests that the agency has unreviewable discretion not to provide the required notice and hearing. That is absurd. The notice provision describes *how* FDA must go about withdrawing approval to ensure that Lannett's rights are protected; it does not provide an additional off-ramp for FDA to evade the statute's command. FDA's

Courts considering similarly worded statutes that impose a mandatory duty on an agency triggered by a specific finding have held that the agency does not have absolute discretion to refuse to make the predicate finding. Consider the statute that *Chaney* described as "an example of statutory language which supplied sufficient standards" to permit judicial review. 470 U.S. at 833. The statute provided that "if [the Secretary of Labor] finds probable cause to believe that a violation . . . has occurred . . . he shall . . . bring a civil action" to set aside a union election. *Id.* (quoting 29 U.S.C. § 482(b)). This statute, the Court held, "quite clearly withdrew discretion from the agency." *Id.* at 834; *see Dunlop*, 421 U.S. at 567 & n.7. That was true even though the statute required the Secretary to bring an enforcement action only if he made a probable-cause finding. The Court never suggested that the Secretary could evade the statute's command by choosing not to make the predicate finding. *Cf. Massachusetts*, 549 U.S. at 533–34 (where statute required EPA to regulate motor vehicle greenhouse gas emissions if it made an "endangerment finding," EPA did not have limitless discretion to refuse to make such a finding regardless of the evidence).

The D.C. Circuit's decision in *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013), is to the same effect. There, the court considered a provision of the FDCA that requires FDA to obtain samples of imported drugs and provides that "*[i]f it appears* from the examination of such samples or otherwise" that a drug "is adulterated, misbranded,

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regulations acknowledge as much: They state that "if . . . FDA finds . . . [t]hat [an application] contains any untrue statement of material fact," then FDA "*will* notify the applicant . . . and . . . afford an opportunity for a hearing on a proposal to withdraw approval of the application." 21 C.F.R. § 314.150(a)(2)(iv) (emphasis added).

or [an unapproved new drug] . . . , then such article *shall* be refused admission." *Id.* at 7 (quoting 21 U.S.C. § 381(a)) (emphasis added). FDA relied on the "if it appears" clause to argue that it had absolute discretion not to make a finding that would trigger the statutory mandate to "refuse[] admission." *Id.* at 8. The court rejected that argument, holding that once FDA had collected drug samples pursuant to the statute, it could not evade the statute's command by refusing to examine the samples and make findings about them. *Id.*

FDA and Lannett make much of the fact that the statute in *Cook* also made *collection* of the samples mandatory, but they fail to explain why that difference matters. Genus is not claiming that FDA has a statutory mandate to engage in investigative work akin to collecting and testing samples of imported drugs. Genus has done the investigation and has presented FDA with clear evidence—including Lannett's statements to its investors—that leaves no doubt that Lannett's Numbrino application contained material untruths. FDA's argument that it can simply ignore that evidence and refuse to make a finding that would trigger its statutory duty to withdraw approval is the same argument the D.C. Circuit rejected in *Cook*.[7]

[7] FDA's position would yield absurd results. For example, § 355(e) also mandates withdrawal "if [FDA] finds . . . that patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information." That provision establishes a clear deadline and a mandatory consequence for applicants who disregard it. Yet on FDA's view, regardless of how much time had passed, the agency could evade Congress's command by refusing to make a "finding" that the applicant had not filed the required information. That cannot be what Congress intended.

The Fourth Circuit's recent decision in *Gonzalez v. Cuccinelli*, No. 19-0435, 2021 WL 127196 (4th Cir. Jan. 14, 2021), cited by FDA and Lannett, supports Genus's position. The statute there provided that "[t]he Secretary [of Homeland Security] *may* grant or deny work authorization" to aliens with pending U-Visa applications. *Id.* at *5 (emphasis added, quotation marks omitted). The Fourth Circuit held that the Secretary's discretion about whether to *grant* such requests implied that he also had discretion about whether to *consider* the requests at all. *See id.* at *5–7. The inverse is true here: FDA's lack of discretion about *what to do* with an application that contains material falsehoods implies that FDA also lacks discretion about *whether to determine* if an application contains material falsehoods, at least in the face of clear evidence. Indeed, the Fourth Circuit in *Gonzalez* held that the Secretary *was* required to adjudicate applications to be placed on a U-Visa waiting list because a regulation provided that "[a]ll eligible petitioners . . . *must* be placed on [the] waiting list." *Id.* at *12 & n.10. By FDA's logic, the Secretary could have argued that although he had a duty to place eligible petitioners on the waiting list, he had no duty to make a finding as to whether any given petitioner was eligible in the first place. Such an argument would not have carried the day in *Gonzalez*, and it should not prevail here either.

Granting FDA absolute discretion not to make the predicate finding at issue here would be especially problematic, because it would erase the careful distinction Congress drew between the first and second sentences of § 355(e). The first sentence provides that FDA "*shall*, after due notice and opportunity for hearing to the applicant, withdraw approval" if it makes one of five enumerated findings, including

"that the application contains any untrue statement of material fact" (emphasis added). The second sentence, in contrast, provides that FDA "*may* also, after due notice and opportunity for hearing to the applicant, withdraw . . . approval" if it makes one of three other enumerated findings, such as that the applicant "has failed to establish a system for maintaining required records" (emphasis added).

Plainly, Congress intended the conditions in the first sentence to trigger *mandatory* withdrawal of approval and the conditions in the second sentence to trigger *discretionary* withdrawal of approval. "[W]hen Congress has employed the two different verbs ['may' and 'shall'] in neighboring statutory passages . . . , 'the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory.'" *In re Rowe*, 750 F.3d 392, 397 (4th Cir. 2014) (quoting *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947)); *see Lopez*, 531 U.S. at 241 ("Congress' use of the permissive 'may' in [one provision] contrasts with the legislators' use of a mandatory 'shall' in the very same section."); *Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

But the difference between the first and second sentence would be obliterated if FDA could exercise limitless, unreviewable discretion, regardless of the evidence, not to make the findings that would trigger the duty the first sentence makes mandatory. If FDA were correct that the need for a predicate finding (or the requirement of notice and a hearing) vests it with complete discretion not to take

action under the first sentence—even in the face of clear evidence—then there would have been no reason for Congress to switch from mandatory to permissive language in the second sentence, and there would be no practical difference between FDA's freedom of action under the two sentences. On the contrary: Congress's use of "shall" to distinguish the first sentence demonstrates that when there is clear evidence of a material untruth in an application, withdrawal of approval is mandatory, not committed to FDA's discretion, and is therefore subject to judicial review.

FDA and Lannett rely heavily on the Second Circuit's split decision in *NRDC*, which addressed a different but similarly worded provision of the FDCA governing withdrawal of approval of animal drugs. *See* 21 U.S.C. § 360b(e)(1). But the court in *NRDC* was faced with a very different question. FDA had announced its view that certain antibiotics were not safe for use in animals because such use risked encouraging the development of antibiotic-resistant bacteria. The plaintiffs argued that FDA's announcement, though made without a hearing, was a "finding" that triggered a duty for FDA to initiate withdrawal proceedings. The majority disagreed, holding that FDA's statements were mere expressions of concern and that FDA could not make a relevant "finding" until after a formal hearing. *See* 760 F.3d at 171. Judge Katzmann dissented, arguing that FDA had made a "preliminary finding" that required it to initiate withdrawal proceedings. *Id.* at 181.

Here, of course, FDA has made no public finding at all concerning whether Lannett's application contained material falsehoods. It has refused to do so despite being presented with clear evidence that Lannett told FDA that it would manufacture

Numbrino in Cody, Wyoming, while at the same time Lannett was telling the public that it had permanently shut down its Cody plant. So the question presented here is not (as in *NRDC*) whether FDA has *already made* a relevant finding, but whether the agency can shut its eyes and ears to evidence that would compel it to make such a finding. No similar question was presented in *NRDC* because the antibiotic safety issue obviously called for in-depth study and the application of scientific judgment to disputed facts. Here, however, there can be no meaningful dispute that Lannett's application contained material untrue statements. *See* Part V, *infra*.

FDA claims vaguely that the question is "more complex than Genus alleges." FDA Mot. 24 n.13. In support of that claim, FDA cites (but does not endorse) a handful of statements in a declaration Lannett filed in a separate case. That declaration is not properly before the Court on these motions to dismiss. But even if it were, it does not introduce any "complexity" that could justify FDA's inaction. The declaration cites regulations and guidance that allow a drug manufacturer to seek FDA's permission to relocate its manufacturing operations after approval. *See* Abt Decl. ¶¶ 5, 11. But those regulations do not entitle a manufacturer to lie about its manufacturing facilities in its application and induce FDA to rely on CMC data from a facility that has been closed. The declaration also asserts, without elaboration or support, that Lannett "maintained the [Cody] site in a state of cGMP compliance and manufacturing readiness through approval of the NDA." *Id.* ¶ 10. But that self-serving assertion is contrary to the public record, which includes admissions by Lannett's CEO that Lannett had "ceased operations at the Cody plant" and sold the

associated equipment, as well as contemporaneous news reports corroborating those statements. *See* pp. 7–8, *supra*; Compl. ¶¶ 40–47.

Under these circumstances, FDA is shirking its statutory duty by refusing to initiate withdrawal proceedings.

III. Genus was not required to file a citizen petition before seeking judicial review of FDA's inaction.

Next, FDA and Lannett contend that 21 C.F.R. § 10.45(b) required Genus to file a citizen petition before challenging FDA's failure to take steps to withdraw Numbrino's approval. This, too, is incorrect. FDA cannot require a party to file a citizen petition before challenging the agency's unlawful failure to comply with a statutory mandate. And in any event, filing a citizen petition would be futile, as the petition could do nothing but repeat the same information Genus provided to FDA in letter form almost a year ago. FDA flatly denies that the information in Genus's letters required the agency to commence withdrawal proceedings, and it offers no reason why providing the same information in a slightly different format would change the agency's stance.

A. A party need not file a citizen petition before suing to compel an agency to perform a statutorily required action.

FDA cannot insist on a citizen petition where, as here, a drug manufacturer seeks to compel agency action that (1) is mandated by statute and (2) has been unlawfully withheld or unreasonably delayed. Section 355(e) does not require the filing of a citizen petition in order to trigger FDA's mandatory duty to withdraw approval. *See* FDA Mot. 5 (acknowledging that FDA "may undertake a withdrawal of approval proceeding *on [its] own initiative or* in response to a citizen petition"

(emphasis added)). And the APA provides a cause of action to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). Together, these provisions mean that if FDA has unlawfully withheld or unreasonably delayed carrying out its statutory duty under § 355(e), then an aggrieved party can sue to compel FDA to comply with the statute. Nothing in the FDCA or the APA allows FDA to impose an additional requirement that the aggrieved party, before suing, file a citizen petition asking the agency to do what the statute *already requires it to do*.[8]

To be sure, FDA often can insist that parties file a citizen petition before seeking judicial review under the APA. That is because the APA generally limits judicial review to "final agency action." *See* 5 U.S.C. § 704. And as FDA admits, the citizen-petition process is a means of *eliciting* final agency action where it would not otherwise exist. *See* FDA Mot. 5. But final agency action is *not* a prerequisite to a suit like this one alleging that an agency has unlawfully withheld or unreasonably delayed a statutorily required action in violation of § 706(1) of the APA. "By definition, a claim of unreasonable delay cannot await final agency action before judicial review, since it is the very lack of agency action which gives rise to the complaint." *Am. Oversight v. U.S. Dep't of Veterans Affairs*, 2020 WL 6381895, at *8 (D.D.C. Oct. 30, 2020) (quoting *Air Line Pilots Ass'n, Int'l v. CAB*, 750 F.2d 81, 85

[8] In other cases involving claims of unreasonable delay, FDA has not objected to the plaintiff's failure to file a citizen petition. *See, e.g.*, *Perrigo Research & Dev. Co. v. FDA*, 290 F. Supp. 3d 51 (D.D.C. 2017) (neither complaint nor FDA's motion to dismiss referred to plaintiff's having filed or needing to file a citizen petition); *Stat-Trade Inc. v. FDA*, 869 F. Supp. 2d 95 (D.D.C. 2012) (same).

(D.C. Cir. 1984)); *see also Cobell v. Norton*, 240 F.3d 1081, 1095 (D.C. Cir. 2001) (where "an agency is under an unequivocal statutory duty to act, failure so to act constitutes, in effect, an affirmative act that triggers 'final agency action' review").[9]

Of course, in some cases no "duty to act" will exist until a party formally requests the action at issue; and in those cases, FDA can insist that a party request the action by filing a citizen petition before bringing suit under § 706(1) of the APA. But that is not the case here. The duty to withdraw approval under § 355(e) is triggered by FDA's own awareness of material false statements in an application. No formal request from outside the agency is needed to call that duty into existence. Accordingly, there is no basis for FDA to demand that Genus file a citizen petition before suing to compel FDA to comply with its statutory duty. *Cf. Or. Wild v. Cummins*, 239 F. Supp. 3d 1247, 1273–74 (D. Or. 2017) ("[A]n action to compel an agency to prepare a [statutorily mandated report] is not a challenge to a final agency decision, requiring exhaustion of administrati[ve] remedies, but rather an action arising under 5 U.S.C. § 706(1), to 'compel agency action unlawfully withheld or unreasonably delayed.'" (quotation marks omitted)).[10]

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[9] Requiring the filing of a citizen petition before a party may file an unreasonable-delay suit would be particularly perverse, as FDA routinely takes years to provide meaningful responses to citizen petitions and instead issues non-substantive interim responses at the nominal 180-day response deadline stating that it "has been unable to reach a decision on the petition." *See* 21 C.F.R. § 10.30(e)(2)(iv).

[10] FDA complains that "without a citizen petition and FDA's response to such a petition, there is no record for the Court to review." FDA Mot. 2. Again, FDA mistakes this for a suit challenging final agency action. It is not; it is a suit to compel agency action unlawfully withheld or unreasonably delayed. And in such a case, "courts do not limit review to the administrative record" because "there is no final agency action

The cases cited by FDA and Lannett are not relevant, as they did not involve suits under § 706(1) seeking to compel statutorily mandated agency action that was being unlawfully withheld or unreasonably delayed. Instead, those cases were dismissed either (i) because plaintiffs challenged an action that was not final or (ii) because they challenged a final action without having presented their arguments and evidence to FDA. *See, e.g.*, *Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 163–64 (D.D.C. 2011) (dismissing challenge to FDA warning letters because the letters were not final agency action and plaintiffs did not file a citizen petition to elicit final agency action), *aff'd*, 664 F.3d 940 (D.C. Cir. 2012); *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21–24 (D.D.C. 2008) (dismissing challenge to approval of supplemental new drug application because plaintiffs neither participated in the approval process nor filed a citizen petition and FDA thus had no "opportunity to address" plaintiffs' concerns).

B. Filing a citizen petition here would be futile.

Even if a citizen-petition requirement could apply in a case like this, Genus would be excused from that requirement here because filing a citizen petition would plainly be futile. *See, e.g.*, *Omnipoint Corp. v. FCC*, 78 F.3d 620, 635 (D.C. Cir. 1996) (discussing futility exception to administrative-exhaustion requirement). Almost a year ago, in letters sent in February and March 2020, Genus provided FDA with information conclusively demonstrating that Lannett's application contained

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to demarcate the limits of the record." *Democracy Forward Found. v. Pompeo*, 474 F. Supp. 3d 138, 148–49 (D.D.C. 2020) (quotation marks omitted).

material untruths. Compl. ¶¶ 59–61. Five months later, in August 2020, Genus accepted FDA's invitation to meet with senior agency officials to review the information Genus had provided. *Id.* ¶ 62. At no point before filing its motion to dismiss did FDA ever suggest that Genus should present that information in the form of a citizen petition. Nor does FDA's motion explain how resubmitting the same information to the agency in the form of a citizen petition could alter the agency's behavior. If Genus is right about the meaning of § 355(e), then FDA has been under a mandatory duty to begin withdrawal proceedings for nearly a year. Yet the agency has not acted and has given no indication that it plans to act. Instead, it claims "absolute discretion" not to initiate withdrawal proceedings *regardless* of whether Lannett's application contained material untrue statements. FDA Mot. 9.

Under these circumstances, it is incredible for FDA to suggest that filing a citizen petition—which could do nothing more than repeat the same information Genus already provided to the agency—might somehow prompt FDA to take action it has refused to take for nearly a year and insists is not legally required. "[A]pplication of the exhaustion doctrine is 'intensely practical,'" *Bowen v. City of N.Y.*, 476 U.S. 467, 484 (1986), and courts do not "requir[e] costly and time-consuming exhaustion of the administrative process" when doing so "would be demonstrably sterile." *Abbey v. Sullivan*, 978 F.2d 37, 46 (2d Cir. 1992); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992) (where defendant gave "no reason to believe that the agency machinery might accede to plaintiffs' claims," it would have been "wholly formalistic

not to regard further appeals as completely futile"); *Smoking Everywhere, Inc. v. U.S. FDA*, 680 F. Supp. 2d 62, 68 n.7 (D.D.C. 2010).

IV. Genus adequately alleged that FDA has unreasonably delayed taking action that is statutorily required.

Lannett argues that Genus's complaint does not adequately allege that FDA has failed to take a statutorily required action or that FDA's delay in taking that action is unreasonable. Lannett Mot. 21–26. Both arguments fail. Section 355(e) requires FDA to withdraw approval for a new drug application found to contain an untrue statement of material fact. In seeking to compel FDA to initiate withdrawal proceedings for Numbrino, Genus is seeking a discrete agency action mandated by statute. Further, it has been almost a year since Genus first notified FDA of Lannett's material untruths, and FDA has not provided any explanation for its failure to initiate the withdrawal process or any timeline for doing so. Such a delay is unreasonable under the relevant equitable factors.

A. FDA failed to take statutorily mandated action.

Lannett first argues that Genus's claim cannot proceed under § 706(1) of the APA because Genus does not allege that FDA "failed to take a *discrete* agency action that it [was] *required to take*." Lannett Mot. 21 (quoting *Norton*, 542 U.S. at 64). Lannett does not dispute that Genus's claim satisfies the discreteness requirement, nor could it: Requiring FDA to take steps to withdraw approval for a single new drug application is far from the sort of "broad programmatic attack" on agency practices that the discreteness requirement is meant to preclude. *See Norton*, 542 U.S. at 64.

Instead, Lannett argues that Genus has failed to identify any action that FDA is "required" to take. Lannett's theory is that Congress's command that FDA "shall" withdraw approval of a new drug application found to contain material falsehoods is rendered precatory by the statute's requirement of a predicate finding. On Lannett's view, notwithstanding Congress's use of mandatory language, FDA has limitless discretion as to whether and when to make the predicate finding and therefore also limitless discretion as to whether and when to withdraw approval. Lannett Mot. 21.

This is simply a rehash of the argument (addressed above) that, regardless of the facts and evidence, the decision whether to commence withdrawal proceedings under § 355(e) is always "committed to agency discretion by law." That argument fails for the reasons explained in Part II, *supra*. In short, Lannett's reading would nullify Congress's use of "shall" and obliterate the distinction Congress drew between the first (mandatory) and second (permissive) sentences of § 355(e). The Court should reject that reading and hold that § 355(e) requires FDA to commence withdrawal proceedings at least where, as here, the agency becomes aware of clear evidence that an approved application contained material untrue statements.

The additional cases Lannett cites on this point do not support it, because none of them involved a lawsuit seeking to compel agency action that was required by statute. *See PETA v. USDA*, 797 F.3d 1087, 1098 (D.C. Cir. 2015) ("[N]othing in the [statute] requires the USDA to apply the general animal welfare standards to birds . . . before it has promulgated more appropriate bird-specific regulations"); *Potomac Riverkeeper, Inc. v. U.S. EPA*, No. 04-cv-3885, 2006 WL 890755, at *13 (D.

Md. Mar. 31, 2006) ("EPA's obligation to review a state's [planning document under the Clean Water Act] 'from time to time' is discretionary."). In contrast, Genus seeks to compel agency action that FDA was statutorily required to take.

B. FDA's year-long delay is unreasonable.

Lannett next argues that Genus has not adequately pled that FDA's prolonged inaction after becoming aware of the material untrue statements in Lannett's application constitutes unreasonable delay. Notably, FDA itself does not make this argument. And while Lannett cites district court cases from out of circuit to argue that the question of unreasonable delay "can be properly reviewed on a motion to dismiss," Lannett Mot. 25, the Fourth Circuit recently reminded district courts in *this* Circuit that "a claim of unreasonable delay is necessarily fact dependent and thus sits uncomfortably at the motion to dismiss stage and *should not typically be resolved at that stage*." *Gonzalez*, 2021 WL 127196, at *13 (emphasis added). In any event, Genus has plausibly alleged that FDA's delay is unreasonable.

As an initial matter, Lannett errs by characterizing the delay at issue here as "less than three months." Lannett Mot. 23. Three months is the amount of time that passed between Genus's meeting with FDA officials in August 2020 and its filing of the complaint in November 2020. But Genus first brought Lannett's untrue statements to FDA's attention in a letter sent on February 11, 2020. Compl. ¶ 60. That letter contained all the information necessary to show that Lannett had closed the Cody facilities months before FDA approved the Numbrino application. *Id.* At the August meeting, Genus simply reiterated the information it had already provided to FDA in the hopes of avoiding the need to file a lawsuit. *Id.* ¶ 62. So FDA's delay is

properly measured from its receipt of the February letter. By the time the Court considers these motions, that delay will measure more than a full year.

In assessing the reasonableness of that delay, the Court may consider the following six factors, among others:

> (1) the time agencies take to make decisions must be governed by a rule of reason;
>
> (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;
>
> (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;
>
> (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;
>
> (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and
>
> (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is "unreasonably delayed."

Gonzalez, 2021 WL 127196, at *13 (quoting *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984)); *see also South Carolina v. United States*, 907 F.3d 742, 759 (4th Cir. 2018). While these factors may "offer helpful guidance," the Court "is not limited to these factors and is not required to use them." *Gonzalez*, 2021 WL 127196, at *13.

Here, multiple factors weigh in favor of finding FDA's delay unreasonable. As to the first factor, while there is "no per se rule as to how long is too long" for an agency to delay in executing a statutory mandate, *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004), "a reasonable time for agency action is usually 'counted in weeks or months, not years.'" *FERC v. Powhatan Energy Fund,*

LLC, 949 F.3d 891, 903–04 (4th Cir. 2020) (quoting *Am. Rivers*, 372 F.3d at 419); *see also Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987); *SAI v. Dep't of Homeland Sec.*, 149 F. Supp. 3d 99, 119 (D.D.C. 2015). Moreover, "the complexity of the task at hand" influences how much delay is reasonable. *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1102 (D.C. Cir. 2003). Here, as Genus has demonstrated, the question of whether Lannett's application contained material untruths is not remotely complex. FDA could have long since dealt with this issue if it had devoted its energies to complying with Congress's directive rather than sweeping Lannett's untrue statements under the rug and seeking to evade review.

With respect to the second factor, although the FDCA does not provide a statutory deadline for withdrawing approval of an application that contains material untrue statements, it does establish other time limits that confirm that FDA's delay here is excessive. For example, the FDCA sets a 180-day timeframe for FDA to complete its *entire review* of a new drug application—including data about the manufacturing facilities named in the application. 21 U.S.C. § 355(c)(1). There is no reason why it should take FDA a year to commence withdrawal proceedings once it becomes aware that the application misidentified those manufacturing facilities. *Cf. Am. Rivers*, 372 F.3d at 420 (reviewing agency's "dilatoriness" based on "the relatively swift treatment it routinely gives similar petitions").

The third and fifth factors also support Genus. The accuracy of information in new drug applications is critical to ensuring the safety and efficacy of drugs. That

implicates human health and welfare and public safety, interests of the highest order. When FDA refuses to take action upon learning of blatant, material untruths in an approved application, it signals that there are no consequences for misleading the agency during the application process. That is directly contrary to the incentives Congress sought to create by mandating withdrawal of approval in these circumstances, and it severely undermines the review system Congress put in place to protect the public from unsafe and ineffective drugs.

Lannett argues that the fourth factor supports the reasonableness of FDA's delay based on FDA's "competing priorities." Lannett Mot. 24–25. But Lannett is not in a position to tell the Court what FDA's priorities are. Even if FDA itself were arguing that "resource constraints and competing priorities" justified its delay, the Fourth Circuit has held that courts "cannot rely on the agency's allegations to find as a matter of law that this factor necessarily favors the agency" at the motion-to-dismiss stage. *Gonzalez*, 2021 WL 127196, at *13. If it is inappropriate for a court to accept an agency's claims regarding its own competing priorities as a basis for dismissal, then it is surely inappropriate for a court to accept a drug manufacturer's unsupported assertions about FDA's priorities at the motion-to-dismiss stage.

Indeed, it is impossible for the Court to assess any argument that FDA's year-long delay is reasonable when FDA itself has not tried to defend that delay and thus has not offered any reasons that might explain it. While FDA briefly mentions the COVID-19 pandemic, it does not claim that the pandemic played any role in its failure to address Lannett's untrue statements. Indeed, FDA does not even claim that it is

still considering the matter; it says only that it cannot "confirm[] or deny[] any inquiry it may have opened." FDA Mot. 1. Based on FDA's statements to date, it is entirely possible that the agency has in fact reached a firm decision not to withdraw Lannett's approval for Numbrino and that it now considers the matter closed. If that proves to be the case, then Genus's claim for action *unreasonably delayed* will become a claim for action *unlawfully withheld*. On this limited record, there is no basis for the Court to conclude that Genus's unreasonable-delay claim fails as a matter of law.

V. Genus adequately alleged that Lannett's application contained untrue statements of material fact.

Finally, Lannett (but not FDA) argues that Genus's complaint does not adequately allege that the Numbrino application contained untrue statements of material fact. Lannett Mot. 26–33. But Genus's allegations on this point are more than sufficient. As the complaint alleges, Lannett represented Cody, Wyoming as the location of Numbrino's manufacturing facility to FDA up until the day Numbrino was approved in January 2020, despite having publicly announced the closure of the Cody facilities months before. Lannett even repeated that misrepresentation in a supplemental filing made *after* it had shuttered the Cody facilities.

Misrepresenting the manufacturing facility of a proposed new drug makes it impossible for FDA to conduct a Pre-Approval Facility Evaluation or Inspection, access data from exhibit batches of the drug produced at the manufacturing site, or review accurate data in the applicant's CMC section—all of which are critical to ensuring that the applicant's facilities, controls, and manufacturing processes satisfy

FDA's safety and efficacy standards. Such a misrepresentation easily qualifies as "material" to FDA's review of a pending new drug application.

A. Lannett stated untruthfully to FDA that it would manufacture Numbrino in Cody, Wyoming, and encouraged FDA to rely on CMC data from a non-operational and shuttered facility.

Lannett's application to market Numbrino contained untrue statements regarding the location of the manufacturing facility for the drug substance and drug product. When Lannett submitted its application in September 2017, it stated in the CMC section that the drug substance and product would be manufactured at the Cody Yellowstone Facility, while the drug substance raw materials would be held and tested at the Cody 119 Facility. Compl. ¶¶ 33, 36. FDA accepted the application for review in November 2017 and performed a Pre-Approval Inspection of the Cody Yellowstone Facility shortly afterwards. *Id.* ¶ 37. Then, while the application was pending, Lannett publicly announced its closure of the Cody facilities in a June 2019 SEC filing, an August 2019 earnings call, and a November 2019 earnings call. *Id.* ¶¶ 40, 42, 46. Indeed, Lannett's CEO stated in November 2019 that the closure of the Cody facilities was complete and manufacturing operations for Numbrino had been relocated to the Carmel Facility. *Id.* ¶ 46.

Yet Lannett continued to represent the Cody Yellowstone Facility as the planned manufacturing site for Numbrino—including in a November 1, 2019 submission that contained an updated CMC section identifying the Cody Yellowstone Facility as the exclusive site for drug substance and drug product manufacturing in response to an FDA information request specifically seeking "to ensure complete facility information is provided for all facilities used for commercial production." *Id.*

¶¶ 48, 51. Those representations were patently untrue and allowed Lannett to obtain approval much earlier than it should have. *Id.* ¶ 54.

Lannett attempts to rationalize this deception by claiming that it was under no obligation to correct inaccurate information in its pending application before the application was approved. *See* Lannett Mot. 29–31. To the contrary, FDA's regulations provide detailed guidance on the process for submitting amendments to an unapproved application, including for a "major amendment" that contains "[a] substantial amount of new data or information not previously submitted to, or reviewed by, the FDA." 21 C.F.R. § 314.60(a)–(b); *see* Compl. ¶ 24. Such an amendment would have been required in this case given that changing a pending application's named manufacturing facility would require the applicant to submit new CMC information, including twelve months of long-term stability data and six months of accelerated stability data for exhibit batches of the proposed drug. *See* Compl. ¶ 26. Not surprisingly, FDA does not endorse Lannett's position that an applicant has no duty to keep its pending application up to date, a position that would severely undermine the accuracy and utility of new drug applications.

But even if Lannett were correct that a manufacturer generally has no duty to ensure that the information in its new drug application remains accurate while FDA is considering the application, that would not help Lannett here. That is because Lannett's misconduct extended beyond its failure to update its pending Numbrino application. As noted, *after* Lannett had publicly announced its closure of the Cody facilities, FDA asked Lannett to update the CMC section of its application "to ensure

complete facility information is provided for all facilities used for commercial production." Compl. ¶ 48. Rather than honestly answering this specific question directly on point, Lannett stated in its response—submitted on November 1, 2019—that Numbrino would be manufactured exclusively in Cody, not Carmel, and listed both Cody facilities as "active." *Id.* ¶ 51. So even if Lannett had no independent duty to correct the untrue statements in its original 2017 submission, its statements to FDA in November 2019 were false when Lannett made them.

Next, Lannett points out that FDA regulations and guidance allow a drug manufacturer to request FDA's permission to make a "manufacturing site change after it receives approval of its NDA." Lannett Mot. 29; *see* 21 C.F.R. § 314.70; Guidance for Industry, Changes to an Approved NDA or ANDA, at 8–11. Of course they do. No one is claiming that a manufacturer is permanently locked into using the facility specified in its application. But the procedures Lannett describes are designed to facilitate changes that a company makes *after* receiving approval—not changes the company makes while its application is pending but strategically conceals from FDA until after the application is approved. Nothing in the regulations or guidance remotely suggests that a company can represent to FDA in its application that it intends to manufacture the drug at a particular facility when the applicant has *already* shut down that facility and relocated its manufacturing operations across the country. In short, FDA's allowance for *post-approval* relocations does not justify *pre-approval* misrepresentations.

Lannett also claims that despite publicly announcing the facility's closure, it actually kept the Cody Yellowstone Facility in "a state of cGMP compliance and manufacturing readiness" until FDA approved the application. Lannett Mot. 30. Lannett does not explain precisely what it means by this cryptic statement, which, in any event, the Court cannot consider on a motion to dismiss. What is clear is that Lannett's CEO stated publicly that Lannett had "ceased operations at the Cody plant" and sold the associated equipment, and contemporaneous news reports confirm those statements. *See* pp. 7–8, *supra*; Compl. ¶¶ 40–47. And what if, contrary to those public disclosures, Lannett did somehow maintain the Cody facilities in a state of "readiness" until its application was approved? Even if true, that would make no difference. It is undisputed that by that time Lannett had no intention of producing Numbrino in Cody. If Lannett is implying that it retained a bare minimum of personnel and equipment in the Cody facilities just in case "FDA elected to inspect that site" before approval, Lannett Mot. 30, then it is admitting that it erected a Potemkin village to fool FDA into approving the Numbrino application under false pretenses. That is hardly a defense.

Finally, Lannett points to its CEO's statement that Lannett intended to effect the "technical transfer" after approval. Lannett Mot. 31. Lannett seems to believe this statement is helpful to its case. Far from it. In context, the phrase "technical transfer" clearly refers to seeking FDA's permission post-approval for the *actual* transfer that had already occurred pre-approval. Far from helping Lannett, the "technical transfer" euphemism is an admission that Lannett intended to game the

system by waiting until after approval to inform FDA about the cross-country relocation of its manufacturing operations.

B. Lannett's untrue statements were material.

Lannett's untrue statements certainly qualify as "material." A false statement is material if it "has a natural tendency to influence, or is capable of influencing," the recipient's decision. *Neder v. United States*, 527 U.S. 1, 16 (1999) (quotation marks omitted); *see also United States v. Raza*, 876 F.3d 604, 617 (4th Cir. 2017). While the statement must be *capable* of influencing the agency, there is no requirement that it *actually* do so. *See Kungys v. United States*, 485 U.S. 759, 771–72 (1988); *see also United States v. Corsino*, 812 F.2d 26, 30 (1st Cir. 1987) (materiality is established when "the fraud in question ha[s] a natural tendency to influence or be capable of affecting or influencing a governmental function," regardless of whether the agency was "actually deceived").

Lannett's untrue statements regarding the manufacturing facility for Numbrino easily satisfy this standard. As shown above, identifying the correct manufacturing facility is a critical part of a new drug application. Applicants must submit information regarding manufacturing processes, equipment, and exhibit-batch stability data that is specific to each named manufacturing facility in the application. Furthermore, FDA's practice is to evaluate that information and, if necessary, conduct a physical inspection of the facility to ensure that the CGMP regulations have been satisfied. *See* pp. 5–6, *supra*; Compl. ¶¶ 12–17. For these reasons, identifying the manufacturing facility for a new drug is precisely the kind of

statement that "has a natural tendency to influence, or is capable of influencing," FDA's decision to approve an application. *See Neder*, 527 U.S. at 16.

It is no response to argue, as Lannett does, that FDA's inaction demonstrates that Lannett's untruths were not material. FDA has not taken a position on the materiality of the statements, nor has it indicated whether it has decided whether to withdraw approval for Numbrino. *See* FDA Mot. 1 (refusing to confirm or deny any inquiry it may be conducting). Even if FDA had reached such a decision, materiality rests on an objective (rather than subjective) test that asks whether the untruths would have the "capacity to influence an objective, reasonable [agency]." *Raza*, 876 F.3d at 621 (quotation marks omitted). Genus's Complaint adequately alleges that the untrue statements in Lannett's Numbrino application were material.[11]

CONCLUSION

Administrative agencies often think they know best and aspire to keep the Judicial Branch out of what agencies conceive of as their business. But FDA is a creature of Congress, and where Congress imposes a mandatory directive, FDA must honor it. And Congress provided a cause of action in the APA to enable parties like Genus to ensure that FDA does so. The Court should deny the motions to dismiss.

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[11] In a footnote, Lannett briefly suggests that "[b]ecause Genus alleges an 'untrue' statement," Rule 9(b)'s requirement to plead fraud with particularity "may apply." Lannett Mot. 32 n.20. But Rule 9(b) does not apply to claims under a statute like § 355(e) that prohibits untrue statements without requiring the other elements of fraud, such as scienter. *See In re Royal Ahold N.V. Sec. & ERISA Litig.*, 351 F. Supp. 2d 334, 402 (D. Md. 2004). In any event, Genus's complaint identifies the "who, what, when, where, and how" of Lannett's untrue statements and would therefore satisfy Rule 9(b). *See Bakery & Confectionary Union & Indus. Int'l Pension Fund v. Just Born II, Inc.*, 888 F.3d 696, 705 (4th Cir. 2018) (quotation marks omitted).

Respectfully submitted,

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